IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS CORPORATION and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	C.A. No. 08-952-SLR

TEVA PHARMACEUTICALS USA, INC.'S
ANSWER AND AFFIRMATIVE DEFENSES

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") hereby answers the Complaint ("the Complaint") filed by Novartis Corporation and Novartis Pharmaceuticals Corporation (collectively "Novartis") as follows:

Nature of the Action

1. To the extent that paragraph 1 makes allegations directed to Teva Parenteral Medicines, Inc. ("TPM") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), or states conclusions of law, no response is required from Teva USA. To the extent that paragraph 1 makes allegations directed to Teva USA, Teva USA admits that Novartis purports to bring this action under the patent laws of the United States. Teva USA denies the remaining allegations in paragraph 1.

Related Action

2. To the extent that paragraph 2 makes allegations directed to TPM and Teva Ltd., or states conclusions of law, no response is required from Teva USA. To the extent that paragraph 2 makes allegations directed to Teva USA, Teva USA admits that Civil Action No. 08-459-SLR is currently pending before this Court, involves the same patent being asserted in this action, and relates to ANDA Nos. 78-576 and 78-580 for zoledronic acid IV (infusion) Eq. 4mg base/5ml (poly and glass vials) filed by TPM. Teva USA denies the remaining allegations in paragraph 2.

Parties

3. On information and belief, Teva USA admits the allegations in paragraph 3.

4. On information and belief, Teva USA admits the allegations in paragraph 4.

5. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 and denies the same.

6. Paragraph 6 makes allegations as to TPM only, and thus no response is required from Teva USA.

7. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd. Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva USA denies the remaining allegations in paragraph 7.

8. Paragraph 8 makes allegations as to Teva Ltd. only, and thus no response is required from Teva USA.

9. To the extent that paragraph 9 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 9 makes allegations

directed to Teva USA, Teva USA admits that it manufactures some generic pharmaceuticals. Teva USA denies the remaining allegations in paragraph 9.

Jurisdiction and Venue

10. To the extent that paragraph 10 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 10 makes allegations directed to Teva USA, Teva USA admits that Novartis purports to bring this action under the United States Patent Laws, and admits that Novartis purports to base jurisdiction over the subject matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202. Teva USA denies the remaining allegations in paragraph 10.

11. To the extent that paragraph 11 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 11 makes allegations directed to Teva USA, for purposes of this case only, Teva USA admits that this Court has personal jurisdiction over Teva USA. Teva USA denies the remaining allegations in paragraph 11.

12. To the extent that paragraph 12 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 12 makes allegations directed to Teva USA, for purposes of this case only, Teva USA admits that venue with respect to Teva USA is proper in this judicial district. Teva USA denies the remaining allegations in paragraph 12.

Novartis's '130 Patent

13. Teva USA admits that on its face the '130 patent states that it is entitled "Substituted Alkanediphosphonic Acids and Pharmaceutical Use," identifies the issue date as July 3, 1990, and identifies the inventors as Knut A. Jaeggi and Leo Wilder. Teva USA further

admits that a copy of the '130 patent is attached to the Complaint. Teva USA denies the remaining allegations in paragraph 13.

14. On information and belief, Teva USA admits that Novartis markets commercial formulations of zoledronic acid under the trade names Zometa® and Reclast®. Teva USA further admits that the FDA's website identifies "Novartis" as the company that submitted NDA 21-223 and 21-386 for Zometa®. Teva USA further admits that the FDA's website identifies "Novartis" as the company that submitted NDA 21-817 for Reclast® and "Novartis Pharms" as the company that submitted NDA 22-080 for Reclast®. Teva USA further admits that the Orange Book lists the '130 patent with respect to both Zometa® and Reclast®. Teva USA denies the remaining allegations in paragraph 14.

Teva's Notice Letter and ANDA Filing

15. To the extent that paragraph 15 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 15 makes allegations directed to Teva USA, Teva USA denies the same.

16. To the extent that paragraph 16 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 16 makes allegations directed to Teva USA, Teva USA denies the same.

17. To the extent that paragraph 17 makes allegations directed to TPM and Teva Ltd., or states conclusions of law, no response is required from Teva USA. To the extent that paragraph 17 makes allegations directed to Teva USA, Teva USA is informed and believes that this action was commenced before the expiration of forty-five days from the date Novartis received the TPM Notice Letter. Teva USA denies the remaining allegations in paragraph 17.

Count I: Infringement of United States Patent No. 4,939,130

18. Teva USA repeats and incorporates herein by reference its responses to paragraphs 1-17.

19. To the extent that paragraph 19 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 19 makes allegations directed to Teva USA, Teva USA denies the same.

20. To the extent that paragraph 20 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 20 makes allegations directed to Teva USA, Teva USA denies the same.

21. To the extent that paragraph 21 makes allegations directed to TPM and Teva Ltd., no response is required from Teva USA. To the extent that paragraph 21 makes allegations directed to Teva USA, Teva USA denies the same.

Teva USA further answers that any allegations in the Complaint requiring a response from Teva USA not specifically admitted are denied. Teva USA also denies that Novartis is entitled to the judgment and relief prayed for in paragraphs (a)-(h) of the Complaint.

TEVA USA'S AFFIRMATIVE DEFENSES

First Affirmative Defense: Non-Infringement

The manufacture, use, offer for sale, sale or importation of Teva USA's Zoledronic Acid Injection specified in ANDA No. 90-823 does not and will not infringe any valid and enforceable claim of the '130 patent, either literally or under the doctrine of equivalents.

Second Affirmative Defense: Invalidity

The claims of the '130 patent are invalid under 35 U.S.C. §§ 101 *et seq*.

Teva USA specifically reserves the right to assert each and every other defense which may become evident in the course of discovery, including but not limited to inequitable conduct.

WHEREFORE, Teva USA prays that the Court enter judgment against Novartis and in favor of Teva USA, dismissing with prejudice each of the claims asserted by Novartis, and that the Court award Teva USA any other relief it deems to be just and proper.

January 7, 2009

BAYARD, P.A.

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on January 7, 2009, he served the foregoing documents by email and by hand upon the following counsel:

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The undersigned counsel further certifies that, on January 7, 2009, he served the foregoing documents by email and by U.S. Mail upon the following counsel:

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